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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,155	12/07/2001	Walter A. Nichols	033018-078	9860

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EXAMINER

WEISS JR, JOSEPH FRANCIS

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 02/23/2004

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/005,155

Applicant(s)

NICHOLS ET AL.

Examiner

Joseph F Weiss Jr.

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7, 9, 14-15.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 5-7, 10-12, 17, 25-26, 40-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Lindsey (US 4012472).

In regards to claim 1, Lindsey discloses a disposable aerosol generator (101/131, see any fig) for use with an inhaler device (~107, See figs 6-9) which includes a heater (147) adapted to volatilize fluid stored in the disposable aerosol generator, comprising: a disposable body (101/131) including a sealed chamber (interior of 101/131) and an outlet (123), the outlet can be opened (note to put device into action you must remove patch 143) to expel vapor (note that gas is pushed through the outlet into the reservoir to generate a vapor, best seen in fig 11, note the converse where aerosolized medicament passes out of 123 in fig 10) the disposable body including first and second layers of material defining the chamber (117/115; 135/133), the chamber accommodating a predetermined volume of a fluid which is expelled through the outlet when the fluid in the chamber is volatilized by the heater (note figs 10 & 11 showing this intended result).

In regards to claim 2, Lindsey discloses the outlet located at an end of a flow passage (103) located between the first and second layers of material.

In regards to claim 5, Lindsey discloses the first layer of material (117/135) comprises a polymer material wherein the chamber comprises a recess in the polymer material, the manner with which the chamber is made (injection molding) not further limiting by dint of the fact the claims are drawn to an apparatus and not a method and the method of making imparts to additional/patently distinguishing structure.

In regards to claim 6, Lindsey discloses the first layer of material comprises a polymer material and the second layer of material comprises a foil layer heat sealed to the polymer layer (col. 3 lines 57-62).

In regards to claim 7 Lindsey discloses the outlet located at an end of a flow passage (103) extending from the chamber, the flow passage comprising a channel in the polymer layer.

In regards to claim 10, Lindsey discloses an inhaler device (Fig 6-9) usable with the disposable aerosol generator according to claim 1, wherein the inhaler device includes a heater arranged to heat the fluid in the chamber (147) so as to expel volatilized fluid from the outlet. (fig 10)

In regards to claim 11, Lindsey discloses the heater as an electrical resistance heater (Col. 9 lines 1-5).

In regards to claim 12 Lindsey discloses the heater comprises a layer of resistance heating material on a substrate (wire over-wrap of heating element), the substrate including an opening located adjacent the outlet (211).

In regards to claim 17, Lindsey discloses a dispensing member (111) located adjacent the outlet of the aerosol generator, the volatilized fluid expelled from the outlet passing through a passage in the dispensing member (note figs 10-11).

In regards to claim 25 Lindsey discloses the sealed chamber comprises a reservoir in a lower surface of the disposable body (formed by "lower surface" of 117) and a flow passage (103) in an upper surface of the disposable body (upper surface of 117 at its perimeter), the flow passage being in fluid communication with the reservoir.

In regards to claim 26, Lindsey discloses a first layer of material (117) on the lower surface covers the reservoir and a second layer of material (115) on the upper surface covers the flow passage, the disposable body comprising a polymer material, the first layer of material comprising a polymer film and the second layer of material comprising a heat resistant material. (Note the disclosure of Lindsey on the materials used for layers 115/117, note the relative nature of the language "resistant" hence any material is considered to have some level of "resistance to heat").

In regards to claim 40, Lindsey is fully capable of containing any of the listed medicaments.

In regards to claim 41, the rejection to claim 1 is incorporated by reference and furthermore the chamber is fully capable of containing a single dose. A single dose of any given medicament will vary in terms of the species receiving the dose, the mass of the patient and what is determined to be a single dose, thus any chamber sized any way, can be considered to be sized to receive a single dose.

In regards to claim 42, Lindsey is fully capable of containing any of the listed medicaments.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3-4, 9, 15, 18-19, 20-24, 27-33 & 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsey.

In regards to claim 3, Lindsey discloses a disposable body that fits in the inhaler, but does not disclose the disposable body having a "series of aerosol generators", i.e the duplication of a known part for a known purpose.

It is noted that applicant's specification does not set forth this variation of what is known in the art, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patentably distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to the device being configured to allow advancement of the aerosol generators to a release point, one of ordinary skill would consider such to be an obvious

Art Unit: 3743

and necessary configuration when duplicating the aerosol generators in a single disposable body, and hence not constitute a patently distinct inventive step.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 4, the prior art discloses such for a single aerosol generator and hence when duplicating, such features would likewise be duplicated.

In regards to claim 9, Lindsey discloses substantially disclose the claimed invention to include the channel being rectilinear but does not include the specific sizing of the channel.

It is noted that applicant's specification does not set forth this specific sizing, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 15, the disposable body of Lindsey is fully capable of being movably supported into a release position.

In regards to claim 16, Lindsey discloses the layer of resistance heating material comprises a strip (wire over-wrap) arranged in a pattern, but does not "size" the pattern of over-wrap to be coextensive with the size of the chamber.

Art Unit: 3743

It is noted that applicant's specification does not set forth this variation of what is known in the art, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 18, the rejection to claims 3-4 is herein incorporated by reference.

In regards to claim 20, Lindsey discloses the disposable body includes a flow passage extending rectilinearly from the chamber (103), but does not disclose the heater arranged to heat both the chamber & the flow passage with a layer of resistance material that facilitates one portion of the heater to become "hotter" than the other portion.

It is noted that applicant's specification does not set forth this reversal/rearrangement of known parts for a known purpose, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 27, one of ordinary skill would consider the use of a plurality of chambers to constitute a mere obvious duplication of a known part for a known

Art Unit: 3743

purpose and further that the features of a disc form with gear teeth on the periphery to be old and well known.

In regards to claim 29, Lindsey discloses the inhaler device comprises a housing (107) and a cover (143), the cover being movable with respect to the housing so as to permit insertion of the disposable body in the inhaler device when the cover is in an open position.

In regards to claim 31, Lindsey discloses the inhaler device including a fluid delivery mechanism (See fig 10 & supporting text regarding pressurization of the chamber to push liquid to the heater) which engages the disposable body such that fluid in the chamber is forced out of the chamber, along a flow passage (103) in the disposable body and toward the outlet, the heater being arranged to heat the liquid in the flow passage.

In regards to claim 32, the reference noted above substantially disclose the claimed invention to include a pressurized oxygen source but does not disclose the use of a piston as the means for pressurizing the fluid in the chamber to sent it to the inhaler for aerosolization.

It is noted that applicant's specification does not set forth the use of a piston as the means for pressurizing, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 33, the reference noted above substantially disclose the claimed invention to include a pressurized oxygen source but does not disclose the use of all the mechanical support elements for a piston as the means for pressurizing the fluid in the chamber to sent it to the inhaler for aerosolization.

It is noted that applicant's specification does not set forth the use these standard piston support mechanics, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to method claims 21-24 & 37-39, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claims 1-20 & 25-36.

5. Claims 13, 14, 19, 28, 30, 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsey as applied to claims 12, 18, 29 & 33 above, and further in view of Jackson (US 6116238) .

In regards to claims 13, 14, 19, 28, 30, 34-36, Lindsey substantially discloses the instant application's claimed invention, but does not explicitly disclose an opening/pierce (manual or automated) and lifting/advancement element. However, Jackson disclose such (pierce/lift element 150, spindle 48, note the use of automation of operation) . The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Jackson and used them with the device of Lindsey. The suggestion/motivation for doing so would have been to use the device in a discrete, automated repetitive dosing manner. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature, and all remaining features that flow from such feature, its usage and arrangement is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Response to Arguments

1. Applicant's arguments filed 2 Jun 03 have been fully considered but they are not persuasive.

Art Unit: 3743

NOTE GENERALLY:

2. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

3. Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

NOTE SPECIFICALLY:

Applicant's amendment and submissions resolves all issues but the matters of anticipation & obviousness. The main thrust of applicant's amendments & arguments are in regard to the outlet, its opening and the resultant expulsion of vapor in general & specifically the expulsion via the outlet. The rejection has been adjusted to address these claim changes as noted above. Please see the disclosure regarding figs 10 & 11 of Linsday and also the disclosure regarding opening the outlet via element 143.

In regards to applicant's concern about the heating element, structurally applicant has admitted on the record that a heater is present and used to volitalize the medicament. Applicant's assertion that when & where during operation of the same structure results in a patently distinct difference is not persuasive. If applicant sets forth the same structure as the prior art then all capabilities will logically flow under an anticipation analysis and/or under an obviousness analysis such a minor distinction

Art Unit: 3743

would be considered an obvious reversal/rearrangement. Applicant should expressly claim the structural relationships that support this capability, operation so that he can make an empirical fact based argument instead of a speculative legal argument, as to whether or not a patentable distinction exists.

Regarding the 103 arguments to the combination of Lindsey & Jackson, Lindsey is not informed as applicant has asserted (see the above rejection) Jackson was combined for different reasons that applicant has not addressed. Thus the conclusions applicant as arrived at why the combination fails are erroneous and thus not persuasive.

Allowable Subject Matter

1. Claim 8 is allowed.

Conclusion

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3743


the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F Weiss Jr. whose telephone number is 703-305-0323. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


J. F. Weiss
2/17/04


Aaron J. Lewis
Primary Examiner